Summer 1998

ORACBA News

Salmonella Enteritidis Risk Assessment: Shell Eggs and Egg Products

This article is a summary from a report submitted to FSIS at the completion of the risk assessment. The complete report will soon be available on the Internet at www.fsis.usda.gov/OPHS/risk/. Members of the *Salmonella* Enteritidis Risk Assessment Team are: Arthur Baker, MD, MPH; Eric Ebel, DVM, MS; Allan Hogue, DVM, MS; Robert McDowell, MS; Roberta Morales, DVM, MPVM, PhD; Wayne Schlosser, DVM, MPH; and Richard Whiting, PhD.

Background

On Friday, June 12, 1998, a special edition of ORACBA's Risk Forum was held in USDA's Jefferson Auditorium. The Food Safety and Inspection Service unveiled its report, *Salmonella* Enteritidis Risk Assessment: Shell Eggs and Egg Products, the first comprehensive, farm-to-table risk assessment for a microbe in food. The risk assessment will be the basis for further examination of strategies to reduce *Salmonella* Enteritidis in food.

The Food Safety and Inspection Service began this project in December 1996 in response to an increasing number of human illnesses attributed to consumption of eggs. From 1976 to 1995, the occurrence of *Salmonella* in humans increased from 1,207 isolates identified in 1976 (0.6 isolates/100,000 population) to 10,201 in 1995 (4.0/100,000 population). *Salmonella* Enteritidis (SE) was the serotype most frequently reported to the Centers for Disease Control (CDC) and Prevention in 1990, 1994, 1995, and 1996, accounting for 24.5 percent of all *Salmonella* in 1996.

Outbreaks and sporadic cases of *Salmonella* infections continue to show an association with the consumption of raw or undercooked shell eggs, a source which was first identified by St.

Louis et al. in 1988.[1] A vehicle was implicated in 45 percent of the human outbreaks of SE: shell eggs constituted 82 percent of this group (38 percent of total outbreaks) between 1985 and 1991.[2]

Objectives

The objectives of this risk assessment are to: develop a farm-to-table model of the risk of illness to humans from eggs internally contaminated with SE bacteria; identify and evaluate potential areas to target for reducing public health risk; evaluate, through mitigation modeling, possible effects of proposed interventions; and identify future research needs.

Process

The *Salmonella* Enteritidis Risk Assessment Team includes a multidisciplinary core group of seven scientists drawn from a range of government agencies and academia. Team members were selected for their technical skills and capability for working in a team environment. The core group has primary responsibilities for model research, development and documentation, quantitative risk assessment, sensitivity analyses, identification of data needs, project planning, coordination, and report writing. The resource group is a pool of technical specialists from which to draw on for support in the identification of data sources and intervention strategies, and for support in model refinement, evaluation, and interpretation. Stakeholder input was solicited on

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[1] St. Louis ME, Morse DL, Potter ME, DeMelfin TM, Guzewich JJ, Tauxe RV, and Blake PA, 1988. The emergence of grade A eggs as a major source of *Salmonella* Enteritidis infections: new implications for control of salmonellosis. Journal of the American Medical Association. 259:2103-2107.

[2] Mishu B, Koehler J, Lee LA, Rodrique D, Brenner FH, Blake P, and Tauxe RV, 1994. Outbreaks of *Salmonella* Enteritidis infections in the United States, 1985-1991. Journal of Infectious Diseases. 169:547-552.

multiple occasions during the risk assessment process.

Constructing a farm-to-table model of SE in eggs and egg products required the careful organization of information obtained from published scientific literature, and unpublished academic, government, and industry sources. The scope of this risk assessment required disaggregation of the problem into smaller, more manageable pieces. Disaggregation was accomplished by dividing the model into five modules: production, egg products processing and distribution, shell egg processing and distribution, preparation and consumption, and public health outcomes. The modular approach allowed the geographically dispersed team members to work on parts of the model individually.

Inputs and outputs for each module were established early in the model development to guide evidence collection and ensure that information generated in one module would be usable in the next module. Extensive literature searches were conducted to identify the issues and data relevant to the quantitative risk assessment. Detailed influence diagrams were developed to represent the relevant risk pathways in each module. A second and more focused literature search was conducted to fill data gaps. Requests for specific data were also extended to researchers, regulatory agencies, and the egg industry. The available data were incorporated into Excel® spreadsheets (Microsoft Corporation, Redmond, WA). The modules were linked into a single model and estimates of the incidence of human illness were calculated with @Risk® (Palisade Corporation, Newfield, NY), a commercial risk assessment software package.

Conclusions

The baseline model predicts there will be 2.4 million exposures annually to SE from internally contaminated eggs. The assessment shows that the 90 percent confidence interval for

the number of exposures to SE is between 536,000 and 5.8 million. Estimates are that there will be from about 126,000 to 1.7 million illnesses with an expected value of about 662,000. Thirty-six thousand ill people are expected to visit a physician and about 3,300 people are expected to need hospitalization. The model also predicts that there will be about 390 deaths annually from SE. Three percent of all people who become ill are expected to develop reactive arthritis as a result of infection. The figures predicted by the model are consistent with those CDC surveillance data would suggest, although they are somewhat larger.

The baseline egg products model does not predict that any cases of SE will result from the consumption of the six pasteurized egg products considered. However, consumer protection can be improved by consideration of time and temperature standards based on the amount of bacteria in the raw product, how the raw product will be processed, and the intended use of the final product.

The SE risk assessment improves our ability to model risk throughout the egg and egg products system, from production to consumption. The model can be refined and updated for use in future risk assessments of infected eggs and egg products. The farm-to-table framework can be used to evaluate the risks associated with other food safety concerns and provides valuable input to decisionmakers and regulators.

Examining the Application of Risk Analysis to USDA's Resource Conservation Programs

Mark A. Tumeo and Andreé DuVarney

Introduction

The Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) and the Natural Resources Conservation Service (NRCS) are working on a pilot project in the application of risk assessment and cost-benefit analyses to USDA's resource conservation programs. Both these types of analyses are important parts of an overall decisionmaking framework to help ensure that major regulations proposed by the USDA are based on sound scientific information and economic analyses. The NRCS project will serve to demonstrate the use of these techniques and how they can assist NRCS in meeting the ongoing mandate to conduct risk assessments to address questions about current and future conservation management activities under the Environmental Quality Incentives Program (EQIP). The goal of the project is to produce an example risk and cost-benefit analysis that, while limited in scope, will still be useful to EQIP program managers in helping them evaluate the effectiveness of a set of manure management options in reducing environmental harm.

The first step in any risk analysis is a thorough examination of the hazards or "stressors" to be examined (*a stressor is an event, agent, or action which is capable of resulting in negative impacts to human health, human safety, or the environment*). In the case of the pilot project, the NRCS completed a thorough examination of the hazards addressed by the EQIP program. This document will serve as the basis of the example risk assessment. Because the project is limited to examination of only a subset of the EQIP program, the stressors to be examined as well as the

endpoints they impact will also be limited. However, the analysis performed should provide an important basis for future analyses.

The risk assessment will examine the impact of a limited set of management actions (i.e., mitigation measures) on endpoints which reflect the impact on environmental quality in a watershed. The endpoint measures will be aggregated on a watershed level consistent with the EQIP priority watershed approach. Further, such aggregation will ensure that individual field-level data are indistinguishable and confidential information is protected. The endpoints selected are the concentrations of eight constituents at the outlet of the watershed: total phosphorus, total nitrogen, total suspended solids, the population of two separate microbial populations in solution and attached to suspended solids, and total Biochemical Oxygen Demand (BOD).

Currently, three watersheds have been identified for the project: 1) the Upper Bosque Watershed in Texas; 2) the Tomhannock Reservoir Watershed in New York; and 3) the Big Spring Watershed in Iowa. These watersheds were selected based on the type and extent of livestock production in the watershed, and the availability of monitoring data. A fourth watershed from the Northwestern part of the United States will be added in the near future.

The overall plan for the project has been peer-reviewed, and when completed, the risk assessment and cost-benefit analysis will also be provided to the peer-review committee. It is anticipated that the overall project should be completed in December of 1998.

Director's Corner

by Nell Ahl

This is the second in a series of three articles for this column prepared by the USDA AAAS Risk Fellows for 1997-98. The AAAS Fellows for FY 98 are Drs. Jennifer Kuzma, Mark Powell, and Mark Tumeo. They provide scientific support for ORACBA risk assessment activities.

"The Risky Medium"

by Mark Powell

Whether the issue is the relative risk of margarine vs. butter, the true toll of road rage, or the buzz over novel cancer therapies, the mass media play a large role in framing problems and setting the public health, safety, and environmental risk agenda. The media's framing of these issues can strongly color the perceptions of policymakers, opinion leaders, and the public. These perceptions, in turn, influence the acquisition and use of science by government agencies.

Journalism tends to confront scientific uncertainty with discomfort and suspicion. An editorial in the August 26, 1991, issue of *Time* provides a vivid illustration. After Vernon Houk of the Centers for Disease Control and Prevention testified that new scientific findings suggested that the cancer risk of dioxin, billed as "the most deadly chemical ever made by man," might be considerably less than previously believed, *Time* declared: "This type of waffling only reinforces public skepticism about the credibility of scientists who seem to change their minds with bewildering regularity, whether the subject is the danger of dioxin or the benefits of oat bran."

The popular news media represent an important source of science for policymakers who may read about scientific studies for the first time in newspaper articles. There are a number of important implications of decisionmakers receiving their scientific information first through the

popular media. The adage "first impressions are lasting impressions" often holds true.

Much has been made of the media's perceived biases (either liberal or conservative), superficiality, and its tendency to focus on the sensational. But the familiar devices of journalism can also have more subtle effects. The typical means of achieving "balance" in a story, for example, is to cite those with starkly contrasting opinions, hence the "dueling scientists" story. This approach can easily exaggerate the degree of scientific uncertainty or the polarization of scientific opinion. Sometimes, journalists seek to achieve balance sequentially, with the slant of stories on an issue changing with time. But the progression of public policy is often path-dependent. As new scientific data and analysis become available, it is frequently difficult to change the trajectory of policy. Consider the case in which the media portray an environmental problem as serious and widespread on the basis of preliminary scientific information. In reaction to this notoriety, a regulatory program is initiated to address the problem. Once the program becomes established, however, new scientific information that suggests the problem is not as serious or common as initially feared may meet with resistance. Politically, it can be difficult and time consuming to change course.

Through the 1970s and most of the 1980s, journalists and public health, safety, and environmental advocates formed a symbiosis, bringing to public light new and neglected hazards and portraying risk management policy as a morality play with a cast of villainous industrialists and noble protectors of the public interest. In recent years, however, the media have expanded the story line to include problems with public health, safety, and environmental regulation, the excesses of advocates, and the distortion or disregard of science to exaggerate risks. For example, Keith Schneider of the *New York Times*, wrote a highly publicized series of articles on

EPA's over-estimation of the cancer risks of dioxin and environmental regulatory overkill. The *Los Angeles Times* published a series of articles on the media's role in exaggerating environmental and other risks. The message probably received its broadest audience with the 1995 ABC-TV special in which 20/20 correspondent John Stossel posed--and answered affirmatively--the question, "Are We Scaring Ourselves to Death?" To some extent, this backlash within the media reflected the growth in the "wise-use" movement in the hinterlands and an increased anti-regulatory sentiment in the general public. It also coincided with a period of public introspection by the media in response to declining public trust in the institution itself. Public health, safety, and environmental advocates portrayed the revisionists as lackeys for industry and as symptoms of the corporate takeover of the news industry.

But there is a simpler explanation. The contrarian movement within journalism provided "a fresh, new angle" on an old story. Whether those of us in the risk and economic analysis community like it or not, the "fourth branch of government" will continue to exercise its responsibility in helping to set the public agenda. Regulatory analysts therefore need to learn how to characterize the seemingly wild oscillations in conventional scientific wisdom as lying wholly within the normal bounds of scientific uncertainty...and to do so in a manner that assuages the discomfort and suspicion of investigative journalists. This is one tall order, but not one we can shrink from.

USDA Risk Assessor Profile: Linda Abbott

Linda Abbott is an ecologist with Environmental Analysis and Documentation (EAD) in Policy and Program Analysis of the Animal and Plant Health Inspection Service. EAD functions

as APHIS' environmental advisor, providing advice relating to planning activities and proposals that are subject to compliance with environmental statutes, regulations, and processes. The principal operative statute is the National Environmental Policy Act (NEPA), which requires Federal agencies to use the best available science to assess and consider the potential environmental impacts of their actions.

During her tenure at EAD, Linda has participated in three major NEPA Environmental Impact Statements (EISs). Her first experience with risk assessment came through working with the team that prepared the nontarget risk assessment for the Medfly Program. (Nontarget species are those which may be unintentionally affected by measures implemented to suppress or eradicate the pest species.) Linda was responsible for modeling the environmental fate and transport of the chemical pesticides proposed for use in the Medfly Program and for estimating the exposure of reptiles to the pesticides. The Medfly Program EIS divided the Southern United States into six ecoregions, and a separate risk assessment was conducted for each region. In addition, an extensive list of nontarget species was analyzed for each ecoregion.

The next large risk assessment prepared by EAD, the Ecological Risk Assessment for Gypsy Moth Management in the United States, was a departure from the approach taken in the Medfly Nontarget Risk Assessment. Ecological endpoints were selected by a team of scientists and managers and were closely tied to issues identified during the NEPA scoping process. The stressors analyzed included the pest species, the gypsy moth, as well as the chemical and biological pesticides. The Gypsy Moth team analyzed broad taxonomic groups, such as lepidopterans, for which taxonomic data could be found rather than analyzing extensive lists of nontarget species for which no toxicological data were available. The Gypsy Moth Ecological

Risk Assessment used a probabilistic approach to analyzing the risk of the pesticides to nontarget species rather than using point estimators as had been done in the Medfly Nontarget Risk Assessment. The Gypsy Moth risk assessment also departed from that for Medflies by considering only two habitat types: natural and residential forested areas. These were chosen based on the large differences in predicted pesticide concentrations in surface waters due to differing amounts of impervious surface areas in the two habitats.

Most recently, Linda led the Ecological Risk Assessment for Cannabis Eradication in the Contiguous United States and Hawaii conducted by EAD for the Drug Enforcement Administration. Conducting programmatic analyses such as the three described above is a challenge because many available models have been developed for site-specific applications. National or regional program assessments require taking a broader view. EAD has tried to solve this problem by identifying those biological or environmental characteristics that most influence the expected environmental concentration of the stressor and then only analyze those types of environments. For further information concerning EAD, environmental statutes and regulations applicable to APHIS activities, and APHIS environmental guidance and documents, point your web browser to: http://www.aphis.usda.gov/ppd/ead/.

April Risk Forum:

The ORACBA Risk Forum for April 1998 featured a panel presentation entitled: "The Use of Simulation Models in Ecological Risk Analysis: Modeling Manure Management Using SWAT and APEX." The purpose of the discussion was to describe an analytical approach for evaluating the performance of alternative manure management practices in reducing nutrient and

microbial runoff. Dr. Ron Meekhof, Office of Risk Assessment and Cost-Benefit Analysis, USDA, discussed the Adaptive Ecological Risk Analysis framework--a structured approach for assembling scientific, economic and technical information, developing and evaluating risk reduction alternatives, and evaluating their performance. Dr. Mark Tumeo, Cleveland State University and AAAS/USDA Risk Assessment Fellow, discussed the principal utility and limitations ecological modeling and general modeling approach for the manure management risk analysis. Dr. Verel Benson, Natural Resources Conservation Service, USDA, led the discussion of how field and watershed simulation models, APEX and SWAT, can be modified for evaluating manure management alternatives and the types of information provided. Dr. Ali Sadeghi, Agricultural Research Service, USDA, described the state of research in field level, microbial modeling and current efforts to incorporate a microbial component into APEX and SWAT.

May Risk Forum:

Dr. David Heron of USDA's Animal and Plant Health Inspection Service presented a seminar entitled: "USDA Environmental Assessments of Genetically Engineered Plants" at the May ORACBA Risk Forum. He is a plant pathologist in Plant Protection and Quarantine's Biotechnology and Biological Analyses unit. APHIS regulates genetically engineered plants, issuing permits for controlled field tests of genetically engineered plants and deregulating those plants prior to commercialization.

Dr. Heron described where the APHIS certification process fits in the development of a commercially viable, genetically engineered plant. He compared the differing roles of the three

Federal regulatory entities (EPA, FDA and USDA) that have been given authority to regulate genetically engineered organisms. He listed the common types of plants subject to genetic engineering. He also identified plant traits such as viral resistance, fungal resistance, insect resistance, or herbicide tolerance that are likely to be modified. Transgenic papaya was used to demonstrate the plant pest analysis used by APHIS. Dr. Heron concluded his presentation by describing how APHIS increases the robustness of their review process by sponsoring workshops with leading scientists to discuss specific issues and through sharing USDA analyses with counterparts in other countries. To learn more about regulation of genetically engineered plants, visit the Biotechnology and Biological Analyses home page at http://www.aphis.usda.gov/bbep/bp/.

JUNE RISK FORUM:

The lead article in this issue of the ORACBA News summarizes the June Risk Forum.

Risk Resources

ORACBA Risk Assessment Training Activities

ORACBA has been actively engaged in developing training activities in risk analysis. Currently, through the USDA Graduate School, ORACBA and the Food and Drug Administration (FDA) offer the course "Introduction to Risk Assessment." The course is offered approximately every 6 weeks at some location around the capital area. Students have found the

course an interesting and useful introduction to the subject. Note, the next course is scheduled for July 21-25. For more information on upcoming offerings, please contact Dr. Al Officer at 703/312-7299 or through E-mail: alvin_officer@grad.usda.gov.

USDA and FDA have joined together to plan and develop a series of risk analysis courses through JIFSAN (Joint Institute for Food Safety and Applied Nutrition) at the University of Maryland. These courses include such topics as risk analysis for managers, risk and cost-benefit analysis for non-economists, risk communication, exposure and dose-response assessment, ecological risk assessment, among others. Most courses will require 2-4 days of classwork, and will be available through USDA Graduate School and through JIFSAN. In addition, expanded versions of these courses eventually will be available to students at the University of Maryland.

ORACBA-Sponsored Training in Monte Carlo Risk Assessment Methods Creates Resource of Highly Trained USDA Risk Assessors

Risk analysis training sponsored by ORACBA has created a resource of highly trained risk assessors within USDA. Two recent 2-week-long training courses on risk analysis modeling were given to USDA employees by David Vose, a specialist in Monte Carlo risk analysis. Participants in these courses constructed probabilistic risk simulation models using @RISK, a risk simulation program that works with the EXCEL spreadsheet. Classical as well as Bayesian statistics were used in the design of risk simulation models.

News of ORACBA

ORACBA celebrated Earth Day, April 22, with a seminar and panel discussion on "New Perspectives in Ecological Risk Assessment." Dr. Steven Bartell of SENES Oak Ridge Inc., Dr.

Peter deFur of the Center for Environmental Studies at Virginia Commonwealth University, and Dr. Anthony Gray of Syracuse Research Corporation discussed the application of ecological risk assessment in prospective risk analyses. The Chesapeake Bay program was discussed as an example of an ecological risk assessment that integrated information over a variety of scales in order to guide management decisions. Some of the strengths and weaknesses of this risk assessment were examined. The three panelists agreed that defining the nature of the problem, the temporal and spatial scales involved, and the types of endpoints addressed was the most important stage of ecological risk assessment. The panelists also agreed that it was preferable to use teams of different experts to prepare ecological risk assessments rather than rely on one or two individuals.

Risk Calendar

August 1998

There will not be an ORACBA Risk Forum this month. Please join us in September.

The Risk Assessment Consortium of the National Food Safety Initiative is sponsoring a public meeting on "Relating Numbers of Foodborne Pathogens to Human Illness." This meeting will be held Tuesday, August 4, at the Stamp Student Union, University of Maryland, College Park, MD. For more information, contact Dr. Wes Long at (202) 205-4064 or visit URL: http://128.8.90.214/jifsan/risk_assessment.htm.

IAMFES, the International Association of Milk, Food, and Environmental Sanitarians, will hold their 1998 annual meeting August 16-19 in Nashville, TN. For more information, contact IAMFES at (800) 369-6337, E-mail: iamfes@iamfes.org, or URL: http://iamfes.org.

September 1998

The ORACBA Risk Forum will be held Wednesday, September 9, from 10 to11:30 a.m. in the Whitten Building ,107-A. Dr. James D. Wilson of Resources for the Future will present "Utility and Limitations of Dose-Response in Food Safety Risk Assessment." For more information, please call (202) 720-8022.

PSAM 4: International Conference on Probabilistic Safety Assessment and Management will be meeting September 13-18, 1998, in New York City, NY. For further information contact Robert A. Bari at (516) 344-2629, Ali Mosleh at (301) 405-5215 or check at URL: http://www.enre.umd.edu/iapsam.

Dr. Resha Putzrath, a speaker in the ORACBA seminar series, will be teaching "Principles of Risk Assessment and Risk Management" in the Graduate Part-Time Program in Environmental Engineering and Science at the Johns Hopkins University Montgomery County Center in the Shady Grove area of Maryland. The course will be held Thursdays from 4:30 to 7:10, September 3 - December 10. More information about the course is available by calling 800-JHU-ENGR, sending an E-mail to pte@jhu.edu, or visiting the web site www.jhu.edu/pte. If you would like to discuss the course, contact Dr. Putzrath at <rmputzrath@mindspring.com>, or 202-342- 2110.

October 1998

The ORACBA Risk Forum will be held Wednesday, October 14, from 10 to11:30 a.m. in the Whitten Building, 107-A. For details, please check our calendar in the next issue of ORACBA News or call (202) 720-8022.

On October 16-18, 1998, The Johns Hopkins School of Public Health, Environmental Systems Research Institute, and World Computer Graphics foundation are sponsoring the First International Health Geographics Conference in Baltimore, MD. The purpose of this conference is to comprehensively bring together for the first time people from many different disciplines who share a common foundation: the geographic aspects of health. For further information, contact Omar A. Khan at (410) 659-6149 or at E-mail: khan@jhuccp.org.

November 1998

The Society of Environmental Toxicology and Chemistry (SETAC) will be holding its 19th annual meeting on November 15-19, 1998, in Charlotte, NC. For more information, contact SETAC at (850) 469-1500, E-mail: setac@setac.org, or at URL: http://www.setac.org.

December 1998

The annual meeting of the Society for Risk Analysis will be held December 6-9, 1998, in Phoenix, AZ. For more information, contact SRA at (703) 790-1745, sra@burkinc.com, or at URL: http://www.sra.org.

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quarterly newsletter is available at no charge to risk assessment professionals in USDA. Send comments or address changes to: USDA, ORACBA, Room 5248-S, Mail Stop 3811, 1400 Independence Avenue, SW, Washington, D.C. 20250-3811. Call (202) 720-8022, or fax (202) 720-1815.

ORACBA RISK FORUM

GUEST SPEAKER:

Dr. James D. Wilson

Resources for the Future

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"Utility and Limitation of Dose Response in Food Safety Risk Assessment"

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Wednesday, September 9, 1998
10 a.m. to 11.30 a.m.
Room 107-A, Whitten Building

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Sponsored By:
USDA, Office of Risk Assessment and Cost-Benefit Analysis (ORACBA)
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